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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,772	05/16/2000	FRANCIS PETIT	146.1339	6484

7590 06/17/2002  
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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/554,772

Applicant(s)

PETIT ET AL.

Examiner

SPOEGLER

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 3-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6, 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Sharon N. Thornton*  
**SHARON N. THORNTON**  
**PATENT ANALYST**

### DETAILED ACTION

1. This action is in response to Paper No. 12, filed on April 4<sup>th</sup>, 2002. Currently, claims 3-6 and 8-10 are pending. All arguments have been full considered and thoroughly reviewed, but are deemed not persuasive for the reasons which follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

### THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 3-6 and 8-10 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for combating the development of atherosclerosis **in warm-blooded animals**, but the final process step is for combating the development of atherosclerosis. Therefore, it is unclear as to whether the claim is intended to be limited to a method of combating the development of atherosclerosis **in warm-blooded animals** or a method of combating the development of atherosclerosis. Applicants can overcome this rejection by adding "in warm-blooded animals" after atherosclerosis.

B) Claims 3-6 and 8-10 are indefinite over "sufficient to combat the development of atherosclerosis" because it is not clear as to what is meant by this recitation. It is not clear as to what is sufficient to "combat" the development of atherosclerosis. Furthermore, it is not clear as to whether this is a method of preventing atherosclerosis (i.e. administering to individual who does not suffer from atherosclerosis) or a method of treating atherosclerosis (i.e. administering to individual who does suffer from atherosclerosis).

#### MAINTAINED REJECTIONS

##### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 3-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by

Agouridas et al. teaches a method of combatting bacterial infections in warm-blooded animals including humans comprising, administering to warm-blooded animals an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts (col. 5, ln. 33-38). With respect to claims 3-6 and 8-9, the reference teaches a plurality of specific ketolides that can be used in the method in this method of treating warm blooded animals (see whole

document). With respect to claim 10, the reference teaches that the usual daily dose is 1.5 to 6 mg/kg, and therefore, provides a range equivalent to the range provided in claim 10. For example, if the daily dose was at 4mg/kg, and an individual to whom the ketolide was administered weighed 100 kg, then 400 mg would be administered to said individual per day.

Furthermore, it is noted that the claims of the instant application are drawn to methods of combating the development of atherosclerosis in warm-blooded animals, where the intended use of the method does not carry weight. Therefore, the recitation "method of combating the development of atherosclerosis in warm-blooded animals" and "to combat the development of atherosclerosis" do not distinguish the claimed methods over the methods taught by Agouridas et al. Currently, the claims only recite one active method step (i.e. administering to a warm-blooded animal an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts), which is taught by Agouridas et al.

#### *Applicants Arguments*

6. Applicants argue:

The invention is drawn to a method of combatting the development of atherosclerosis, and is not anticipated by Agouridas.

#### *Response to Applicants Arguments*

7. Applicants arguments are not persuasive for the following reasons:

The claims are drawn to a single method step, "administering to a warm-blooded animal an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts", which is taught by Agouridas (col. 5, ln. 33-38). Therefore, Applicants invention is anticipated by Agouridas, since both the instant claims and Agouridas are drawn to a method of administering to a warm-blood animal. The recitation "method of combating the development of atherosclerosis in warm-blooded animals" and "to combat the development of atherosclerosis" do not distinguish the claimed methods over the methods taught by Agouridas et al. In addition, the claims do not specifically teach a method of "combatting" atherosclerosis, the claims simply recite a method of "administering to a warm-blooded animal an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts".

#### *Conclusion*

8. No claims are allowable.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire ~~THREE~~ MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

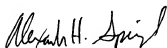
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
June 11, 2002

  
KENNETH R. HORNICK PH D  
PRIMARY EXAMINER  
6/12/02